LISTING OF CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Previously Presented) A method effective to protect a desired property of biological material during the process of sterilization which comprises:

a) packaging the biological material;

b) providing a protective atmosphere within the package and,

c) sterilizing the packaged biological material in the presence of said protective atmosphere effective to reduce and/or inactivate adventitious agent(s).

2. (Previously Presented) The method of claim 1 wherein the adventitious agent is at least one member selected from the group consisting of bacteria, mold, yeast, fungus, virus and prions.

3. (Previously Presented) The method of claim 2 wherein the virus is selected from the group consisting of enveloped and non-enveloped viruses.

4. (Original) The method of claim 2 wherein the virus is selected from the group consisting of HIV, Hepatitis A, Hepatitis B, Hepatitis C, polio, herpes, parvo, west nile, and SARS.

5. (Original) The method of claim 1 wherein the biological material is selected from the group consisting of food, tissue, therapeutically useful substance and therapeutically useful device.

6. (Previously Presented) The method of claim 1 wherein the biological material is bone.

7. (Previously Presented) The method of claim 6 wherein the biological material is donor bone.

8. (Original) The method of claim 7 resulting in the conservation of the biomechanical strength of the bone.

9. (Original) The method of claim 7 resulting in the conservation of the osteoconductivity, growth factor activity, signal transduction and/or transcription factor activity of the bone.

10. (Previously Presented) The method of claim 1 resulting in the conservation of the *in vitro* degradation characteristics of the biological material.

11. (Previously Presented) The method of claim 1 wherein the biological material is subjected to at least one pre-packaging procedure, said procedure being one of:

(i) applying an antioxidant to the biological material,

(ii) removing lipid from the biological material,

(iii) removing metal ions from the biological material,

(iv) lowering the temperature of the biological material below ambient temperature,

(v) removing water from the biological material, and

(vi) reducing the bioburden of the biological material.

12. (Original) The method of claim 11 wherein the antioxidant is at least one member selected from the group consisting of ascorbic acid, beta carotene, selenium, coenzyme Q10, tocopherols, retinoids and carotenoids.

13. (Original) The method of claim 11 wherein lipid is removed from the biological material by a lipid-removing procedure which includes contacting the biological material with at least one lipid-dissolving solvent and/or at least one lipase.

14. (Original) The method of claim 11 wherein metal ions are removed from the biological material by contacting the biological material with at least one chelating agent for metal ions.

15. (Original) The method of claim 14 wherein the chelating agent is at least one member selected from the group consisting of aminopolycarboxylic acids, aminopolycarboxylic salts,

diethylenetriaminepentaacetic acid, nitrilotriacetate, diethylenetriaminepentaacetic acid, ethylene diamine, N,N-bis(carboxymethyl)glycine, gluconates, organophosphonates, sodium silicate, magnesium sulfate, ferulic acid, sodium hydrosulfite, hydrogen peroxide, gluconic acid, anthraquinone, citric acid and dimercaprol.

16. (Original) The method of claim 11 wherein water is removed from the biological material by at least one of vacuum drying, lyophilization and displacement of water with at least one other liquid.

17. (Original) The method of claim 11 wherein the reduction of the bioburden of the biological material is accomplished by at least one of exposing the biological material to ionizing radiation and/or ultraviolet radiation, pasteurization, contact with at least one antibiotic, antiviral and/or antimycotic agent.

18. (Original) The method of claim 17 wherein the biological material is exposed to a total ionizing radiation dose of from about 2 to about 50 kGy.

19. (Original) The method of claim 17 wherein the biological material is exposed to a total ionizing radiation dose of from about 5 to about 25 kGy.

20. (Original) The method of claim 17 wherein the biological material is exposed to ultraviolet radiation at a wavelength of from about 1 nm to about 400 nm for about 1 minute to about 1 hour.

21. (Original) The method of claim 17 wherein the biological material is exposed to ultraviolet radiation of from about 5 nm to about 250 nm for from about 5 to about 30 minutes.

22. (Original) The method of claim 17 wherein pasteurization of the biological material is carried out from about 60 to about 120.degree. C. for from about 1 minute to about one hour.

23. (Original) The method of claim 17 wherein pasteurization of the biological material is

carried out from about 90 to about 110.degree. C. for from about 1 minute to about one hour.

24. (Original) The method of claim 1 wherein in packaging step (a), the biological material is placed within a gas-permeable or gas-impermeable package.

25. (Original) The method of claim 1 wherein in packaging step (a), the biological material is placed within a microbe-impermeable package.

26. (Original) The method of claim 1 wherein in packaging step (a), the biological material is placed within an inner package and the inner package is thereafter placed within an outer gas-impermeable package.

27. (Original) The method of claim 1 wherein in packaging step (a), the biological material is placed within an inner package and the inner package is thereafter placed within an outer microbe-impermeable package.

28. (Original) The method of claim 26 wherein the outer package is a bulk package.

29. (Original) The method of claim 27 wherein the outer package is a bulk package.

30. (Previously Presented) The method of claim 1 wherein the step of providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least one of: replacing the original atmosphere with an inert atmosphere, a reducing atmosphere or a mixture of inert adding a reducing component to the original atmosphere with a reducing atmosphere or replacing the original atmosphere with a mixture of an inert atmosphere and a reducing atmosphere, and removing original atmosphere under vacuum.

31. (Previously Presented) The method of claim 1 wherein prior to sterilizing step (c), the packaged biological material is cooled or heated and while in the cooled or heated state is subjected to sterilizing step (c).

32. (Original) The method of claim 30 wherein the inert atmosphere comprises at least one inert gas selected from the group consisting of nitrogen and argon.

33. (Previously Provided) The method of claim 30 wherein the reducing atmosphere comprises at least one reducing gas selected from the group consisting of hydrogen, hydrogen sulfide and carbon monoxide.

34. (Original) The method of claim 30 wherein the mixture of inert atmosphere and reducing atmosphere contains from about 0.5 to about 99% by volume reducing gas.

35. (Original) The method of claim 30 wherein original atmosphere is removed under a vacuum of from about 1 to about 200 torr.

36. (Original) The method of claim 31 wherein the biological material is subjected to cooling to a temperature of from just below ambient to about -200.degree. C.

37. The method of claim 36 wherein the biological material is subjected to cooling to a temperature of from about 0 to about -75.degree. C.

38. (Original) The method of claim 31 wherein the biological material is subjected to heating to a temperature of from just above ambient to about 100.degree. C.

39. (Original) The method of claim 38 wherein the biological material is subjected to heating to a temperature of from about 30 to about 80.degree. C.

40. (Previously Presented) The method of claim 1 wherein in sterilizing step (c), the total dose of irradiation is from about 2 to about 50 kGy.

41. (Previously Presented) The method of claim 1 wherein in sterilizing step (c), the total dose of irradiation is from about 5 to about 25 kGy.

42. (Previously Presented) The method of claim 1 wherein sterilizing step (c) is carried out by multiple radiation dosing.

43. (Previously Presented) The method of claim 42 wherein sterilizing step (c) is carried out in a two-dose or three-dose sequence.

44. (Original) The method of claim 11 wherein the biological material is bone.

45. (Original) The method of claim 13 wherein the biological material is bone.

46. (Original) The method of claim 14 wherein the biological material is bone.

47. (Original) The method of claim 17 wherein the biological material is bone.

48. (Original) The method of claim 24 wherein the biological material is bone.

49. (Original) The method of claim 25 wherein the biological material is bone.

50. (Original) The method of claim 26 wherein the biological material is bone.

51. (Original) The method of claim 27 wherein the biological material is bone.

52. (Original) The method of claim 30 wherein the biological material is bone.

53. (Original) The method of claim 31 wherein the biological material is bone.

52. (Original) The method of Claim 30 wherein the biological material is bone.

53. (Original) The method of Claim 31 wherein the biological material is bone.

54. (Previously Presented) The method of claim 10 wherein the biological material is bone.

55. (Previously Presented) The method of claim 17 wherein the biological material is graft tissue.

56. (Previously Presented) The method of claim 55 wherein the graft tissue is bone.

57. (Previously Presented) The method of claim 1 wherein the biological material is graft tissue.

58. (Previously Presented) The method of claim 57 wherein the graft tissue is bone.

59. (Previously Presented) The method of claim 31 wherein the biological material is graft tissue.

60. (Previously Presented) The method of claim 59 wherein the graft tissue is bone.

61. (Previously Presented) The method of claim 30 wherein the adventitious agent is at least one member selected from the group consisting of bacteria, mold, yeast, fungus, virus and prions.

62. (Previously Presented) The method of claim 61 wherein the virus is selected from the group consisting of enveloped and non-enveloped viruses.

63. (Previously Presented) The method of claim 62 wherein the virus is selected from the group consisting of HIV, Hepatitis A, Hepatitis B, Hepatitis C, polio, herpes, parvo, west nile, and SARS.

64. (Previously Presented) The method of claim 30 wherein the biological material is selected from the group consisting of food, tissue, therapeutically useful substance and therapeutically useful device.

65. (Previously Presented) The method of claim 30 wherein the biological material is bone.

66. (Previously Presented) The method of claim 30 wherein the biological material is donor bone.

67. (Previously Presented) The method of claim 66 resulting in the conservation of the biomechanical strength of the bone.

68. (Previously Presented) The method of claim 66 resulting in the conservation of the osteoconductivity, growth factor activity, signal transduction and/or transcription factor activity of the bone.

69. (Previously Presented) The method of claim 30 resulting in the conservation of the in vitro degradation characteristics of the biological material.

70. (Previously Presented) The method of claim 30 wherein the biological material is subjected to at least one pre-packaging procedure, said procedure being one of

(i) applying an antioxidant to the biological material,

(ii) removing lipid from the biological material,

(iii) removing metal ions from the biological material,

(iv) lowering the temperature of the biological material below ambient temperature,

(v) removing water from the biological material, and

(vi) reducing the bioburden of the biological material.

71. (Previously Presented) The method of claim 30 wherein the antioxidant is at least one member selected from the group consisting of ascorbic acid, beta carotene, selenium, coenzyme Q10, tocopherols, retinoids and carotenoids.

72. (Previously Presented) The method of claim 70 wherein lipid is removed from the biological material by a lipid-removing procedure which includes contacting the biological

material with at least one lipid-dissolving solvent and/or at least one lipase.

73. (Previously Presented) The method of claim 70 wherein metal ions are removed from the biological material by contacting the biological material with at least one chelating agent for metal ions.

74. (Previously Presented) The method of claim 73 wherein the chelating agent is at least one member selected from the group consisting of aminopolycarboxylic acids, aminopolycarboxylic salts, diethylenetriaminepentaacetic acid, nitrilotriacetate, diethylenetriaminepentaacetic acid, ethylene diamine, N,N-bis(carboxymethyl)glycine, gluconates, organophosphonates, sodium silicate, magnesium sulfate, ferulic acid, sodium hydrosulfite, hydrogen peroxide, gluconic acid, anthraquinone, citric acid and dimercaprol.

75. (Previously Presented) The method of claim 70 wherein water is removed from the biological material by at least one of vacuum drying, lyophilization and displacement of water with at least one other liquid.

76. (Previously Presented) The method of claim 30 wherein the reduction of the bioburden of the biological material is accomplished by at least one of exposing the biological material to ionizing radiation and/or ultraviolet radiation, pasteurization, contact with at least one antibiotic, antiviral and/or antimycotic agent.

77. (Previously Presented) The method of claim 76 wherein the biological material is exposed to a total ionizing radiation dose of from about 2 to about 50 kGy.

78. (Previously Presented) The method of claim 76 wherein the biological material is exposed to a total ionizing radiation dose of from about 5 to about 25 kGy.

79. (Previously Presented) The method of claim 76 wherein the biological material is exposed to ultraviolet radiation at a wavelength of from about I nm to about 400 nm for about 1 minute to about 1 hour.

80. (Previously Presented) The method of claim 76 wherein the biological material is exposed to ultraviolet radiation of from about 5 nm to about 250 nm for from about 5 to about 30 minutes.

81. (Previously Presented) The method of claim 76 wherein pasteurization of the biological material is carried out from about 60 to about 120° C for from about -1 minute to about one hour.

82. (Previously Presented) The method of claim 76 wherein pasteurization of the biological material is carried out from about 90 to about 110° C for from about 1 minute to about one hour.

83. (Previously Presented) The method of claim 30 wherein in packaging step (a), the biological material is placed within a gas-permeable or gas-impermeable package.

84. (Previously Presented) The method of claim 30 wherein in packaging step (a), the biological material is placed within a microbe-impermeable package.

85. (Previously Presented) The method of claim 30 wherein in packaging step (a), the biological material is placed within an inner package and the inner package is thereafter placed within an outer gas-impermeable package.

86. (Previously Presented) The method of claim 30 wherein in packaging step (a), the biological material is placed within an inner package and the inner package is thereafter placed within an outer microbe-impermeable package.

87. (Previously Presented) The method of claim 85 wherein the outer package is a bulk package.

88. (Previously Presented) The method of claim 86 wherein the outer package is a bulk package.